

REMARKS

Clams 1-19 and 21-26 are pending. No claims are amended herein. Applicants submit that this application is in condition for allowance and such action is earnestly requested. Each of the Examiner's reasons for rejection is addressed below.

As an initial matter, Applicants believe that the rejections are based on a disbelief of the facts in the Declaration of Skelte Anema. Applicants submit that the Examiner is not free to ignore the facts stated in the Declaration. Further, the Examiner has not provided any evidence to counter the Declaration and therefore cannot base rejections on disbelief of the evidence presented in the Declaration. Applicants submit that the facts in the Declarations support the conclusion that there was no reason to make the combination proposed by the Examiner and that there would have been no reasonable expectation of success for the proposed combination. Accordingly, Applicants respectfully request withdrawal of the obviousness rejections.

Delespaul Does Not Anticipate Claim 10

Claim 10 stands rejected under 35 U.S.C. § 102(b) as anticipated by FR 2452879 to Delespaul et al. (hereinafter "Delespaul").

In making the anticipation rejection the Examiner provides citations to multiple examples, a description of conventional cheese making using coagulation, a description of cheese manufacture using ultrafiltration, different methods for decalcification, and different methods for heat treatment. Office Action, pages 3-5. The *picking and choosing* done by the Examiner from multiple examples and embodiments is inappropriate for *anticipation* rejections and contravenes accepted Federal circuit caselaw. Even if all of the features of Claim 10 were present in multiple different embodiments described in Delespaul, which they are not, such picking and choosing from multiple embodiments is inappropriate for an *anticipation rejection*. As the Federal Circuit has made clear:

Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. *See Arkley*, 455 F.2d at 587 ("[T]he [prior art] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] *without any need for picking, choosing, and combining various disclosures* not directly related to each other by the teachings of the cited reference.").

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Net MoneyIn, Inc., 545 F. 3d 1359, at 1371 *citing In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis added). Thus, the anticipation rejection of Claim 10 is inappropriate here because of the Examiner's picking and choosing from different embodiments and processes that are not directly related to each other.

Moreover, Delespaul does not disclose a calcium depleted HY-MPC. Thus, Delespaul does not disclose the features of Claim 10. Accordingly, Applicants request withdrawal of the anticipation rejection for this reason as well.

The Combination of Delespaul and Bhaskar Does Not Make Claims

Claims 1-9, 11-19, and 21-26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over WO 01/41578 to Bhaskar et al. (hereinafter "Bhaskar") in view of Delespaul.

The Supreme Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason *must be more than a conclusory statement that it would have been obvious*. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007)(emphasis added).

Here, the Examiner has only provided conclusory reasoning for combining Bhaskar and Delespaul. Further, the rejections appear to be based on a disbelief of the facts in the Declaration. Applicants submit that the Examiner is not free to ignore the facts stated in the Declaration. Further, the Examiner has not provided any evidence to counter the Declaration and therefore cannot base rejections on disbelief of the evidence presented in the Declaration. Applicants submit that the facts in the Declarations support the conclusion that there was no reason to make the combination proposed by the Examiner and that there would have been no reasonable expectation of success for the proposed combination. Accordingly, Applicants respectfully request withdrawal of the rejections.

Applicants disagree with a number of findings made by the Examiner that contradict the evidence presented in the Declaration. The Examiner found "It should be realized that claims 1 and 11 require a dried MPC. The MPC disclosed by Delespaul is not a dried MPC. Therefore, the decalcified, heated MPC of Delespaul is obviously dried and used as disclosed by Bhaskar. Delespaul clearly disclosed the use of decalcified and heat treated milk in making cheese with

homogenous texture which is clearly the nugget free cheese as presently claimed” (Office Action at page 10, item 6). Applicants disagree and have presented *evidence* from a person of skill in the art to the contrary. It was not obvious to a person of skill in the art to dry the heated MPC to obtain a useful dispersible product. The Declaration by Skelte Anema states in paragraph 8 that “I also anticipated that heat treating the MPC at near neutral pH would not give a cold soluble product.” Dr. Anema is a specialist in milk protein denaturation and interactions during dairy processing (see paragraph 1 of the declaration). A person of skill in the art would have expected a heat treated MPC treated at a near neutral pH to result in a product that is not cold soluble. An MPC that is not cold soluble would not be a dispersible product suitable for use in the cheese making steps in Bhaskar. Applicants have presented evidence refuting this finding by the Examiner that the Examiner is not free to cavalierly ignore without providing any scientific reasoning or reason to doubt this statement.

Further a person of skill in the art would not have had a reasonable expectation of success for drying the product of Delespaul. The Examiner found that “Delespaul, teaches of the consequences of overheating the treated mixture resulting in increased viscosity. However, it is obvious that the extent of heating would be a controllable step in order to prevent the viscosity increase.” (Office Action at page 10, item 5). Applicants submit that there is no disclosure in Delespaul or Bhaskar of *how* to prevent a viscosity increase. Further, this finding by the Examiner contradicts paragraph 7 of the Declaration, which states “Prior to the present invention, it would have been understood that the heating step of Delespaul would make the MPC solution too viscous to dry to form a powder.” Thus, a person of skill in the art would have expected the heating step of Delespaul to produce an MPC solution that is too viscous to dry to form a powder. The Examiner has provided no evidence of how a viscosity increase could be controlled to avoid such a result, much less any reason to do so. Applicants submit that a person of skill in the art would not have had a reasonable expectation of success for the combination proposed by the Examiner because a person of skill in the art would have expected the heating step of Delespaul to make the MPC solution too viscous to dry to form a powder. (Declaration of Skelte Anema, paragraph 7).

The Examiner also found that “One of the ordinary skill in the art would realize that the temperature range taught by Delespaul denatures the whey proteins. This denaturation results in

their association with caseins leading to improved cheese yield and thus the prevention of loss of these proteins in the whey separated from rennet curd.” (Office Action at page 8, item 2). Applicants submit that there is no basis in Delespaul or Bhaskar to support this finding and the Examiner has not pointed to any other basis for this conclusion. Applicants submit that Delespaul and Bhaskar do not make it obvious that denaturation results in the association of whey proteins with caseins leading to improved cheese yield and thus the prevention of loss of these proteins in the whey separated from rennet curd. Delespaul does not involve separation of curd from whey and Bhaskar does not involve denaturation. Again, the Examiner’s conclusory findings are not supported by Delespaul and Bhaskar and contradict the evidence presented in the Declaration of Skelte Anema. For example, paragraph 9 of the Declaration states that:

Prior to the present invention it was not known that reduced calcium MPC could be effective in preventing loss of the whey protein into the whey in a traditional cheese making process even if heat treated, and based on the knowledge at that time it was not obvious to me that it would. Delespaul does not provide any teaching in that regard because Delespaul uses ultrafiltration to remove water from the cheese milk to avoid the necessity for separating whey from casein. Thus Delespaul does not separate the whey and provides no reason to use reduced calcium MPC to prevent loss of the whey protein in a traditional cheese making process.

Applicants submit that this conclusory finding by the Examiner contradicts paragraph 9 of the Declaration without providing any reasoning or scientific evidence to refute the statements in the Declaration.

Applicants again submit that there would be no reasonable expectation of success for the combination of Bhaskar and Delespaul proposed by the Examiner and that this is supported by the Declaration of Skelte Anema. *Pharmastem Therapeutics v. Viacell, Inc.* 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007) (after *KSR*, Federal Circuit finds claims non-obvious for lack of indication of reasonable expectation of success for asserted combination). Prior to the present invention, it would have been understood that heat treating the MPC at near neutral pH would not produce a cold soluble product. Declaration of Skelte Gerald Anema, paragraph 8. A cold soluble product is desirable in the context of MPC manufacture. See Bhaskar page 6, lines 34-35. The expectation of decreased cold water solubility for heat treated MPC teaches away from incorporating the heat treatment step of Delespaul with the MPC manufacturing process of

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Bhaskar. Further, the skilled artisan would not have had a reasonable expectation of success for producing an MPC with acceptable cold solubility properties. Accordingly, for this reason as well, the skilled artisan would not have a reasonable expectation of success for using the heating step of Delespaul in the MPC process of Bhaskar for at least this reason.

In conclusion, the Examiner has only provided conclusory reasoning for making the asserted combination and ignored evidence presented in the Declaration without any scientific reasoning or evidence to contradict the Declaration. Applicants submit that there is no reason to combine the references as proposed by the Examiner and that there would be no reasonable expectation of success for such a combination. Applicants also submit that the combination fails to disclose the features of the claims for the reasons discussed in previous responses. Accordingly, Applicants respectfully request withdrawal of the rejections.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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